

## **II. REMARKS**

Upon entry of the amendment, claims 1 to 15, 19 to 30, 33 to 37, 40 to 47, 49 to 56, 59 to 61 will be pending. It is stated in the Office Action Summary that claims 1 to 15, 19 to 30, and 33 to 36 are allowed.

### **A. Regarding the Amendments**

Claim 48 is cancelled herein without disclaimer, and without prejudice to Applicant's pursuing prosecution of subject matter encompassed within one or more of the claims in an application claiming the benefit of priority of the subject application.

Claim 37 has been amended to incorporate the language of previously pending claim 48, which depended from claim 37 and has been cancelled herein. As such, the amendment does not introduce new matter.

Claim 40 has been amended to clarify that a composition for reducing the risk of transmission of a sexually transmitted disease is one "consisting essentially of a  $\beta$ -cyclodextrin and solid substrate", and that the that "optionally, the composition contain an agent" as recited. It is submitted that the amendment merely clarifies the claim language, and does not introduce new matter.

Claims 37 and 40 also have been amended to delete reference to a "use" for the claimed compositions, since the language is superfluous with respect to a composition claim. As such, the amendment merely corrects an informality, and does not add new matter.

New claims 59, 60 and 61 have been added. New claims 59 and 60 are supported, for example, at page 29, lines 2-5, and by original claims 40 to 45, and new claim 61 is supported, for example, at page 60, lines 2-4. As such, the new claims do not introduce new matter.

**B. Rejections under 35 U.S.C. § 112**

The rejection of claims 52 to 56 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking an adequate written description is respectfully traversed.

It is stated in the Office Action that the specification does not describe using two compositions, one consisting essentially of a  $\beta$ CD and one consisting essentially of an additional active agent. Applicant point out, however, that the specification, in discussing a composition of the invention, makes clear that, when an active agent is used in combination with a  $\beta$ CD, "the additional agent, either alone or in combination, does not affect the activity of the  $\beta$ CD...." (page 26, line 23, to page 27, line 3; citing specifically to page 26, lines 31-32). Thus, it is clear from the specification that Applicant contemplated adding an additional active agent "alone, or in combination" with a  $\beta$ CD. Accordingly, it is respectfully requested that the rejection of the claims under 35 U.S.C. § 112, first paragraph, be removed.

The rejection of claims 40 to 45, 50 and 51 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly vague and indefinite is respectfully traversed.

It is stated in the Office Action that the claimed subject matter is unclear in reciting the phrase "consisting essentially of a  $\beta$ -cyclodextrin, a solid support, and optionally, an agent selected from a contraceptive..." because the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention (O.A., page 9, Section 13). It is alleged that contraceptives, for example, are well known for preventing sexually transmitted diseases and, as such, would have a material affect on the basic and novel characteristics of the claimed composition.

Claim 40 has been amended to more clearly indicate that a composition of the invention is one "consisting essentially of a  $\beta$ -cyclodextrin and a solid support, wherein the composition optionally contains an agent" as indicated. Applicant points out that the basic and novel

characteristic of the claimed composition is that  $\beta$ -cyclodextrin ( $\beta$ CD), alone, can reduce the risk of transmission of a sexually transmitted disease. The term "optionally" in claim 40 allows that the composition can, but need not, further contain an agent as recited. Applicant submits, however, that the presence of one or more of the recited agents (e.g., a contraceptive) does not have a material affect on the basic and novel characteristics of the composition; i.e., the agents do not affect the ability or activity of the  $\beta$ CD to reduce the risk of a sexually transmitted disease. Instead, the additional recited agents, when present, act independently of the composition consisting essentially of a  $\beta$ CD.

Applicant submits that the claims, as amended, clearly define the subject matter of the invention such that one skilled in the art would know the metes and bounds of the invention. Accordingly, it is respectfully requested that the rejection of the claims under 35 U.S.C. § 112, second paragraph, be removed.

### **C. Prior Art Rejections**

#### **Previous Ground of Rejection**

The rejection of claims 52 to 56 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Bergeron et al. in view of Baert et al is respectfully traversed.

It is maintained in the Office Action that the cited references describe a  $\beta$ CD and an active agent, and the use of such a combination to treat HIV infection. Applicant points out, however, that claims 52 to 55, which depend from claims 9 and 23, respectively, require contacting a first composition consisting essentially of a  $\beta$ CD and a second composition consisting essentially of an agent as recited. As discussed above, the basic and novel characteristic of the claimed invention is that a  $\beta$ CD, alone, is an active agent, and the claims are directed to the use of a  $\beta$ CD alone (e.g., claims 9 and 23). Claims 52 to 56 merely allow for an additional treatment of a subject with agents known in the art as useful for the specified methods. Such combined modalities are well known in the art and, include, for example, the use of a

spermicide with a diaphragm, each of which acts independently, and does not affect the activity, of the other. As such, claims 52 to 56 require the use of two separate compositions, one of which consists essentially of a  $\beta$ CD.

As has been pointed out previously, the cited references do not teach or suggest the use of a composition consisting essentially of a  $\beta$ CD because, prior to Applicant's disclosure, the basic and novel characteristic of the invention, i.e., that a  $\beta$ CD has an activity with respect to sexually transmitted pathogens, was not known. As such, regardless of whether a  $\beta$ CD in a composition with an antiviral agent, for example, would have had the inherent activity that Applicant discovered, one skilled in the art would not have administered a composition consisting essentially of a  $\beta$ CD to a subject, either alone or with a second separate composition, as required by the claims. Accordingly, the claimed methods could not have been obvious and, therefore, it is respectfully requested that the rejection of claims 52 to 56 as obvious over Bergeron et al. in view of Baert et al. be removed.

#### **New Grounds of Rejection**

The rejection of claims 37, 46, 48 and 49 under 35 U.S.C. § 102(b) as allegedly anticipated by Trinh et al. is respectfully traversed.

It is stated in the Office Action that Trinh et al. describe an aqueous odor absorbing composition consisting essentially of uncomplexed cyclodextrin and, optionally, a cyclodextrin compatible agent (e.g., an antimicrobial agent). The cyclodextrin can be a  $\beta$ CD, which can be present at a level up to about 1.85%.

The present claims are directed to a pharmaceutical compositions, and one of ordinary skill in the art, viewing the subject application, would know that the compositions are formulated for use with living subjects, particularly humans. In contrast, Trinh et al. describe compositions for controlling odors, preferably for use on inanimate objects (see, e.g., column 1, lines 24-29) Where Trinh et al. discuss the addition of an antimicrobial agent, it is as a

preservative for preventing growth of bacteria in the cyclodextrin solution (column 25, line 40, to column 27, line 23; see, e.g., column 25, lines 41-56). In particular, Trinh et al. teach that the antimicrobial "preservative is not being used to kill microorganisms on the surface onto which the composition is being deposited..." (column 26, line 63, to column 27, line 6). Trinh et al. mention that the cyclodextrin solution can be used on human skin, but only in the context of warning that care should be taken if an antimicrobial is in the composition (column 35, lines 5-7).

It is well recognized that an anticipatory reference must place the claimed invention in the possession of the public. Applicant submits that Trinh et al. do not place a pharmaceutical composition consisting essentially of a  $\beta$ CD in the possession of the public because Trinh et al. specifically state that, when a cyclodextrin solution contains an antimicrobial compound, it is not for the purpose of killing a microorganism on the surface for which it is used. As such, it is submitted that Trinh et al. do not teach or suggest a pharmaceutical composition, as claimed, and, therefore, cannot anticipate the claimed compositions. Accordingly, it is respectfully requested that the rejection of claims 37, 46, 48 and 49 as anticipated by Trinh et al. be removed.

The rejection of claims 37, 48 and 49 under 35 U.S.C. § 102(b) as allegedly anticipated by Jacob. is respectfully traversed.

It is noted in the Action that Jacob describes the production of  $\beta$ CD in 93% yield. Claim 37 has been amended to clarify that a pharmaceutical composition of the invention consists essentially of "a concentration of 1 mM to 100 mM"  $\beta$ CD. Jacob does not teach or suggest such a composition and, therefore, cannot anticipate the claimed subject matter. Accordingly, it is respectfully requested that the rejection of claims 37, 48 and 49 as anticipated by Jacob be removed.

The rejection of claims 40 to 45, 50 and 51 under 35 U.S.C. § 103(a) as allegedly obvious over Bergeron et al. in view of Baert et al. is respectfully traversed.

With respect to the present obviousness rejections, it is stated in the Office Action that the "application currently names joint inventors". For the record, it is noted that the application names a "sole inventor".

It is stated that Bergeron et al. describe a composition that "comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the pathogen." (OA, paragraph bridging pages 12-13), and that Baert et al. describes compositions comprising a  $\beta$ CD and an active ingredient. It is further stated that the transitional phrase "consisting essentially of" limits the scope of the claims to materials that "do not materially affect the basic and novel characteristic(s)" of the claimed invention (O.A., page 14, emphasis in original), and noted that contraceptives, for example, are well known for their use in compositions for preventing sexually transmitted diseases. It is stated that, absent a clear indication of the basic and novel characteristics, the term "consisting essentially of" will be interpreted as open language.

Applicant points out that claim 40 has been amended to clarify that the claimed subject matter consists essentially of a  $\beta$ CD and solid substrate, and that that composition "optionally" can include an additional agent as recited. As such, it is clear from the claim that  $\beta$ CD, alone, is all that is required of a composition of the invention. Further, it is clear from the disclosure and record in the present case, that the "basic and novel characteristic(s)" of the invention is the discovery by Applicant that  $\beta$ CD, alone, has activity in preventing transmission of sexually transmitted diseases. Applicant submits that the addition of an optional agent, as recited, does not materially affect the basic and novel characteristics of the invention because such agent(s), when present, act independently of and do not affect the  $\beta$ CD or its activity. As such, the term "consisting essentially of" should be interpreted as 'closed' language because none of the

additional recited agents, when present in a composition of the invention, materially affects the ability of the  $\beta$ CD to prevent transmission of a sexually transmitted disease.

The cited references, either alone or in combination, do not teach or suggest that a  $\beta$ CD can prevent a sexually transmitted disease, and do not teach or suggest a composition consisting essentially of a  $\beta$ CD and solid support. For this reason, and for the reasons set forth above, it is respectfully requested that the rejection of claims 40 to 45, 50 and 51 as allegedly obvious over Bergeron et al. in view of Baert et al. be removed.

The rejection of claim 47 under 35 U.S.C. § 103(a) as allegedly obvious over Trinh et al. in view of Bergeron et al. is respectfully traversed.

It is stated in the Office Action that Trinh et al. describe an aqueous odor-absorbing composition consisting essentially of uncomplexed cyclodextrin and, optionally, a cyclodextrin compatible agent such as an antimicrobial agent, and that Bergeron et al. describe that a cyclodextrin composition can act as a barrier and comprises a film-forming component. Applicant submits, however, that, absent knowledge of the subject application, one skilled in the art would have had no motivation to combine the Trinh et al. and Bergeron et al. references.

Trinh et al. is directed to odor-absorbing compositions that include a cyclodextrin, and can include an antimicrobial agent to prevent growth of bacteria in the composition. Trinh et al. specifically state that, when their cyclodextrin composition includes an antimicrobial, it is present as a "preservative", and "is not being used to kill microorganisms on the surface onto which the composition is being deposited..." (column 26, line 63, to column 27, line 6). In contrast, Bergeron et al. is directed to formulations for preventing pathogen induced disease; Bergeron et al. mention that a cyclodextrin can be used as a drug carrier (column 4, lines 5-11; see, also, column 1, lines 63-66).

It is submitted that there is nothing in either reference that would have led one of ordinary skill to consider combining Trinh et al. and Bergeron et al. because the references are directed to

In re Application of  
James E. Hildreth  
Application No.: 09/802,779  
Filed: March 8, 2001  
Page 17

PATENT  
Attorney Docket No.: JHU1710-3

different and non-overlapping subject matter. Trinh et al. describe the use of cyclodextrins in odor-absorbing compositions. Bergeron et al. state that cyclodextrins can be used as a carrier for an antimicrobial agent, which is a well known and routine use for cyclodextrins. However, there is nothing in the Trinh et al. reference that would have motivated one in the art to combine its teachings with that of Bergeron et al. and, similarly, there is nothing in Bergeron et al. that would have led one to combine its teachings with that of Trinh et al. Accordingly, it is respectfully requested that the rejection of claim 47 as allegedly obvious over Trinh et al. in view of Bergeron et al. be removed.

In view of the amendments, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to the subject application.

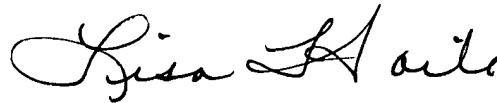


In re Application of  
James E. Hildreth  
Application No.: 09/802,779  
Filed: March 8, 2001  
Page 18

PATENT  
Attorney Docket No.: JHU1710-3

Enclosed are Checks No. 558650 (\$98.00) and No. 559880 (\$198.00) in the total amount of \$296.00 in payment of the excess independent claims fee (\$86.00) and the two (2) month extension of time fee (\$210.00). The Commissioner is hereby authorized to charge any other fees that may be associated with this communication, or credit any overpayment, to Deposit Account No. 50-1355.

Respectfully submitted,



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Lisa A. Haile, J.D., Ph.D.  
Registration No. 38,347  
Telephone: (858) 677-1456  
Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP  
4365 Executive Drive, Suite 1100  
San Diego, California 92121-2133  
USPTO CUSTOMER NO. 28213